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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,733	07/20/2005	Motoaki Kamachi	Q89240	5404

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EXAMINER	
LILLING, HERBERT J	

ART UNIT	PAPER NUMBER
1657	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,733	KAMACHI ET AL.	
	Examiner	Art Unit	
	HERBERT J. LILLING	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *6-10 and 21-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 11-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *6-10 and 21-27* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 July 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *July 20, 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Receipt is acknowledged of an election response filed October 12, 2007.

2. Claims 1-27 are pending in this application which is a 371 of PCT/JP04/00500 filed January 21, 2004 which claims benefit to JAPAN 200313762 filed January 22, 2003 and JAPAN 200394881 filed March 31, 2003.

3. Applicant has elected without traverse Group 1, claims 1-20, and election of species without traverse, which includes claims 1-5 and 11-20 for examination in accordance with the elections of September 04, 2007 and October 12, 2007.

Thus, claims 1-5 and 11-20 are for examination.

Claims 6-10 and 21-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 04, 2007 and October 12, 2007.

4. The following is a quotation of the first paragraph of.35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 1-5 and 11-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention with respect to the following:

Whereby the Acyl Group Receptor is broader than the enabling disclosure based on the specification that "there is no limitation" as well as "a substance which is not usually an appropriate substrate" in view of the following:

> [0078] With regard to the acyl group receptor used in the highly efficient acyl group transfer reaction according to the present invention, there is **no limitation so far as it is able to be used** as a substrate for the above CoA enzyme. When a substrate specificity of the enzyme is changed by the reaction condition or when a mutant where the substrate specificity is modified by means of protein engineering is used, a substance which is not usually an appropriate substrate for the enzyme is also able to be used as an acyl group receptor.

There is no guidance as to the acyl group receptor which would involve undue experimentation lacking a suitable written description.

B. Claims 18- 20 requires synthase from ATCC 17699 which requires the structure of the specific enzyme which is lacking in the instant specification or a product by process in the claims or a deposit for E.coli pQEREC or any other suitable deposit:

> "....a plasmid pQEREC was prepared. This was introduced into Escherichia coli BL 21 (pREP4) to prepare Escherichia coli BL21 (pQEREC) for the preparation of enzyme. The Escherichia coli was incubated in 1,000 ml of LB medium at 30.degree. C. for 16 hours so that enzyme was accumulated in cells and the cells were broken by an ultrasonic treatment whereupon a soluble protein in the cells was recovered. The protein was passed through an Ni-NTA agarose gel column so that (His)-PhaC (six histidine being added to N-terminal) was specifically adsorbed with the column. After washing the column, (His)-PhaC was eluted using imidazole and, after dialysis, 10 mg thereof was obtained as a pure enzyme. Molecular weight of the enzyme by an SDS-PAGE was 65 kDa.";

U.S. Patent Rules of Deposits

It is apparent that the specific synthase is required to practice the claimed invention(s) as recited in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the strain or other . See 37 C. F. R. 1.802.

The specification does not provide a repeatable method for obtaining a suitable strain or plasmid to prepare the product which produces the synthase and it does not appear to be a readily available material. Deposit of the strain or other would satisfy the enablement requirements of 35 U.S.C. 112. If a deposit has been made, Applicant is required to meet the necessary criteria of the deposit rules in accordance with 37 CFR 1.801-37 CFR 1.809.

If a deposit has not been supplied or made under the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty **and that all restrictions** imposed by the depositor on the availability to the public of the deposited material will be **irrevocably removed** upon the granting of a patent, would satisfy the deposit requirements, See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

b) all restrictions imposed by the depositor on the availability to the public of the deposited material **will be irrevocably** removed upon the granting of a patent;

c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

d) a viability statement in accordance with the provisions of 37 CFR 1.807;

and

e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function n the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification, See 37 CFR 1.803-37 CFR 1.809 for additional explanations of these requirements.

> Please note that the mere reference to a deposit or the biological material itself in any document or publication does not necessarily mean that the deposited biological material is readily available. Even a deposit made under the Budapest Treaty and referenced in a United States or foreign patent document would not necessarily meet the test for known and readily available unless the deposit was made under conditions that are consistent with those specified in these rules, including the provision that requires, with one possible exception (37 CFR 1.808(b)), that all restrictions on the accessibility be irrevocably removed by the applicant upon the granting of the patent. Ex parte Hildebrand, 15 USPQ2d 1662 (Bd. Pat. App. & Int. 1990).

C. Claims 1-5 and 10-20 are rejected under 35 USC . 112, first paragraph, because the specification, while being enabling for specific strain E.coli B21 (pQEREC) , does not reasonably provide enablement for any synthase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and practice the invention commensurate in scope with these claims.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 11-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention with respect to the scope of "acyl group receptor" in view of the following scope in the specification has been deemed not to be definite:

> "...the acyl group receptor used in the highly efficient acyl group transfer reaction according to the present invention, there is **no limitation so far as it is able to be used** as a substrate for the above CoA enzyme. When a substrate specificity of the enzyme is changed by the reaction condition or when a mutant where the substrate specificity is modified by means of protein engineering is used, a substance which is not usually an appropriate substrate for the enzyme is also able to be used as an acyl group receptor."

The language of the claims must make it clear what subject matter the claims encompass to adequately delineate their "metes and bounds" before the claimed subject matter can properly be compared to the prior art, it is essential to know what the claims do in fact cover.

Thus, Claims 1-5 and 10-20 fail to comply with the above requirements for this examiner to properly search and examine the full scope of the claimed inventions.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claim 1-3 are rejected under 35 U.S.C. 102(b) as being by Ouyang et al.

The reference teaches the general reaction whereby there is disclosed a method for the reproduction of acyl coenzyme A which is within the scope of the claimed subject matter.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 and 10-20 rejected under 35 U.S.C. 103(a) as being unpatentable over Ougang et al.; Antonio et al; Yuan et al each alone or further in view of each other.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The references do not disclose the specific synthase as disclosed in the specific examples in the specification but the references are considered to render obvious to employ other PHA synthases which claimed inventions in light of the Supreme Court's recent decision in KSR International Co. v. Teleflex Inc (TFX) ., 82 USPQ2d 1385 (2007).

For those claims which may not meet the factual inquiries as set forth in Graham v John Deere Co as noted above the claimed subject matter as a whole based on the references of record would provide guidance for the production of reproduction of acyl-coenzyme A with a thiol compound and one of ordinary skilled in the pertinent art would reasonably expect that an aromatic thiol would be within the scope of a thiol even

though the reference does not specifically state an aromatic thiol as well as thiophenol. The reaction would be considered to be obvious based on common known text book reactions. The other issue is to employ PHA synthase reagents which each of the references teaches various synthases from the genus Ralstonia as noted by Antonio et al or Yuan et al.

It is noted that the PCT action dated May 11, 2004 has indicated that claims 4-5 and 13-16 were considered to be novel and patentable over the art of record. However, in view of the issues indicated above in light of the Supreme Court Decision, the claimed subject matter has been deemed to be not patentable as the claimed subject differences with respect to the issue of "....acyl group donor which is an acyl ester of a compound" for which claims 4, 5 and 13-17 depend is obviously within the skill of the ordinary worker to substitute any known compound for the primary references and reasonably expect the acyltransferase reaction to go forward to produce the desired receptor compound.

8. **No claim is allowed.**

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300**. or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit **1657**
November 23, 2007

Dr. Herbert J. Lilling
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Group 1600 Art Unit 1657